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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,055	MORI ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/3/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are presented for examination

Applicants' response, filed 6/5/2009, is acknowledged and entered. Claims 1-10 remain withdrawn from consideration. Claims 11-15 are presently under examination.

Change of Examiner

The examiner assigned to the instant application has changed. The new examiner is James D. Anderson. Contact information is provided at the end of this Office Action.

Response to Arguments

Applicants' arguments have been fully and carefully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

In light of the new rejections being applied against the pending claims, which rejections were not necessitated by Applicant's amendments, this Office Action is Non-Final.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 4/3/2009. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the recited "base" are unclear.

From Applicant's disclosure, it appears that the term "base" as recited in the claims is intended to mean a support or carrying ingredient as used in medicine. However, the claims are not limited to such a definition and could therefore be interpreted to encompass, for example, an aqueous solution of NaOH as a "base".

Claim Rejections - 35 USC § 103 – New Ground of Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hiroyoshi *et al.*** (Japanese Application Publication No. 61-263917) in view of **Sugita *et al.*** (USP No. 6,723,732; Issued Apr. 20, 2004; 371 (c)(1), (2), (4) Date: Jul 19, 2001).

As discussed in the previous Office Action, Hiroyoshi *et al.* disclose the claimed active agent 3-methyl-1-phenyl-2-pyrazolin-5-one as a cerebral normalizing agent which has cerebral ischemia protecting action (Abstract). Referring now to the English translation of Hiroyoshi *et al.* provided by Applicants, the inventors disclose the use of 3-methyl-1-phenyl-2-pyrazolin-5-one as an active ingredient for cerebral normalization (page 1 of English translation). Thus, the use of the claimed compound to protect against cerebral dysfunction is not new or unobvious in view of the prior art. As Applicant's correctly observe in their response filed 6/5/2009,

Hiroyoshi *et al.* do not teach percutaneous absorption of the active agent for protecting against cerebral dysfunction.

However, newly cited Sugita *et al.* disclose percutaneously administratable preparations containing cerebral function activators (Title; Abstract; col. 2, lines 3-7). In this regard, the inventors teach that orally administrable preparations generally lead to lack of sustained efficacy due to the extreme rise of blood concentration. The percutaneously administrable preparations of the invention overcome this problem and can reduce individual differences of blood concentration by avoiding the hepatic first-pass effect. Furthermore, percutaneously administrable preparations show continuous pharmacological efficacy because the plasma concentration of the active ingredient can be kept constant for a long duration by the sustained release to whole body circulation (col. 2, line 66 to col. 3, line 11). As such, percutaneous administration of cerebral protecting agents is likewise not new or unobvious in view of the prior art.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use percutaneous administration to administer the cerebral normalizing agent disclosed in Hiroyoshi *et al.* in light of the obvious benefits of such a mode of administration as disclosed in Sugita *et al.* The skilled artisan would expect that any cerebral normalizing agent would benefit from percutaneous administration in light of the teachings of Sugita *et al.* As such, Applicant's claimed method of administering a known cerebral normalizing agent using a known method of administering such compounds is not patentable over the cited prior art. It is noted that Sugita *et al.* disclose formulating active agent in an "aqueous base" as recited in the instant claims (col. 8, lines 59-62).

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hiroyoshi *et al.*** (Japanese Application Publication No. 61-263917) in view of **Sugita *et al.*** (USP No. 6,723,732; Issued Apr. 20, 2004; 371 (c)(1), (2), (4) Date: Jul 19, 2001) as applied to claims 11-12 above, and further in view of **Koide *et al.*** (Japanese Application Publication No. 10-265373).

Claims 13-15 differ from Hiroyoshi *et al.* and Sugita *et al.* in that the primary and secondary references do not disclose the claimed excipients of the recited percutaneous absorption type pharmaceutical composition.

However, Koide *et al*., as discussed in the previous Office Action, disclose a tacky adhesive composition comprising a drug, water-soluble polymer, cross-linking agent a polyhydric alcohol and water (Abstract). The water soluble polymers include rubber polymers such as polyacrylates [0013], and these polymers make up 1- 15% [0014]. The formulation comprises crosslinking agents that make up from 0.1-10% of the formulation and include glycine [0017-0019]. The formulation comprises polyhydric alcohols such as ethylene glycol and propylene glycol that make up from 15-50% of the formulation [0020-0021]. The formulation further comprises tackifiers such as cellulosic resins, where the compounds are present in the formulation up to 15% [0020]. The water content of the formulation ranges from 40-70% [0038]. The drugs range from 0.001-10% of the drug formulation [0031]. The tacky formulation is applied to a film or substrate and applied to the skin [0022]. The tacky topical formulation, while disclosing a wide range of active agents is silent to the specific active agent of the instant claims.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made that any known percutaneous absorption composition could be used to administer the claimed compound percutaneously. Sugita *et al*. teach and suggest the benefits of percutaneous absorption of cerebral protecting agents. As such, there is nothing unobvious about using the composition disclosed in Koide *et al*. to form a percutaneous absorption type pharmaceutical comprising 3-methyl-1-phenyl-2-pyrazolin-5-one as recited in the instant claims and suggested and motivated by the teachings of Hiroyoshi *et al*. in view of Sugita *et al*.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Hiroyoshi *et al***. (Japanese Application Publication No. 61-263917) in view of **Sugita *et al***. (USP No. 6,723,732; Issued Apr. 20, 2004; 371 (c)(1), (2), (4) Date: Jul 19, 2001) as applied to claims 11-12 above, and further in view of **Akira *et al***. (Japanese Application Publication No. 63-203613).

Claims 13 differs from Hiroyoshi *et al*. and Sugita *et al*. in that the primary and secondary references do not disclose the claimed excipients of the recited percutaneous absorption type pharmaceutical composition.

However, Akira et al. disclose a hydrophilic percutaneous administration preparation containing a percutaneous absorption drug added to a base containing a water-soluble high polymer, a crosslinking agent, and a polyhydric alcohol (Abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made that any known percutaneous absorption composition could be used to administer the claimed compound percutaneously. Sugita *et al*. teach and suggest the benefits of percutaneous absorption of cerebral protecting agents. As such, there is nothing unobvious about using the composition disclosed in Akira *et al*. to form a percutaneous absorption type pharmaceutical comprising 3-methyl-1-phenyl-2-pyrazolin-5-one as recited in the instant claims and suggested and motivated by the teachings of Hiroyoshi *et al*. in view of Sugita *et al*.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614